

which is a continuation-in-part of U.S. Patent U.S. 6,489,494 filed July 19, 2001, published December 3, 2004.

U.S. Patent Number 6,713,512 comprises the use of kombic acid as an antioxidant (see page 4, column 3, lines 25-26). Furthermore, the patent describes the wide use of natural antioxidants in human dietary supplements, and how antioxidants mediate the effects of autooxidation and photooxidation that result in cell damage and ageing phenomena for animals and humans. The patent also cites examples showing how kombic acid would function in the human body as an antioxidant. Specifically, Example 5 (Page 6, Column 7, line 44) describes the use of rat liver microsomes as an *in vivo* model and demonstrates very strong antioxidant activity; consistently better than vitamin E on a weight basis.

The use of Example 5 showing that kombic acid and its derivatives function as an antioxidant in an *in vivo* model in this priority patent lays the foundation for the subsequent work in the current CIP showing another *in vivo* model; namely the use of kombic acid and its derivatives to treat human patients in need of antioxidant treatment. The present application deals with cognitive diseases such as Alzheimer's disease, Parkinson's disease and other neurocognitive diseases known to be diseases associated with oxidative stress and/or oxidative damage.

Furthermore, in U.S. Patent Number 6,489, 494, applicant makes the statement that the examples cited are *in vitro* simulations of how kombic acid would function in the human body as an antioxidant (see Page 6, Column 7, line 24). These experiments compare the use α -tocopherol (Vitamin E), which, as stated in the application (Page 6, Column 7, line 27), is known to be a standard for showing antioxidant activity. Specifically, the patent states that an antioxidant superior or equivalent to vitamin E in experimental tests simulating the human biological system is a unique and valuable discovery as not many of the vast array of organic chemicals have any power as antioxidants at all.

Thus, the idea for using kombic acid as an antioxidant in the human body was discussed and demonstrated both *in vitro* and *in vivo* in these priority patents. Because it is known by those of skill the art that neurocognitive diseases including, but not limited to Alzheimer's Disease, Parkinson's Disease, and many others may be mediated by oxidation and because antioxidants can be used to alleviate oxidative stress, the foundation for the use of kombic acid as an antioxidant in the treatment of neurocognitive diseases is clearly established in the priority patents.

The Rejection of Claims 14-20 under 35 U.S.C. 112:

Applicant acknowledges that Claims 14-20 are rejected under 35 U.S.C. 112 as the Examiner states that the specification does not reasonably provide enablement for cognitive diseases.

Applicant respectfully disagrees. It is well known in the art that Vitamin E can be used to treat various neurodegenerative disorders. Standard clinical trials (i.e. double-blind, placebo-controlled, randomized, multi-center trials) using various doses of Vitamin E and other compounds, are well known in the art. For Vitamin E studies, efficacy determinations were made by analysis of increased time to onset of disease and/or symptoms, time to occurrence of death, time to occurrence of institutionalization, time to occurrence of loss of ability to perform basic activities of daily living or time to occurrence of severe dementia (for Alzheimer's), time when levodopa becomes necessary (for Parkinson's), or other neurologic or neuropsychiatric symptoms associated with these diseases. Applicant respectfully argues that a person skilled in the art would certainly be able administer compounds of the present invention in a similar manner and analyze their efficacy in a similar way to the studies already done using Vitamin E and other antioxidants.

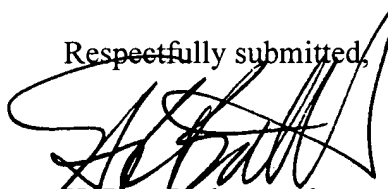
CONCLUSION:

For all the above reasons, Applicant submits that the claims all define patentably over the prior art and are enabled. Therefore, applicant submits that this application is in condition for allowance, which action they respectfully solicit.

Date:

5/31/04

Respectfully submitted,



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